Remarks

Based on the following remarks, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections set forth in the Action.

A. Status of the Claims

Claims 1-15, and 32-82 are currently pending in the application for examination.

B. Rejection of Claims Under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph - enablement

Claims 1, 3, 5, 6, 8, 9, 55, 59, 62, 64, 65, 71, 76, and 78 stand rejected under 35 U.S.C. § 101 for allegedly lacking either a specific, substantial, and credible asserted utility, or a well established utility. In making this rejection, the Action states that "the claimed composition fairly encompasses the template, which was elected by applicant to be mRNA." The Action takes the position that a utility rejection is justified because the claims read on mRNA from any source, including expressed sequence tags for which no known utility exist." *See* Action at page 2-3, bridging paragraph. Applicants respectfully traverse this ground for rejection.

In light of the rejection of claims 1, 3, 5, 6, 8, 9, 55, 59, 62, 64, 65, 71, 76, and 78 for alleged lack of utility, the Action has also rejected these claims under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement Applicants respectfully traverse this ground of rejection as well.

In making these rejections, the Action appears to be invoking the MPEP's caution against claiming a polynucleotide (such as an EST) as a "gene probe" or "chromosome marker" when the target is not known. *See* MPEP 2107.01(I)(A). According to the MPEP, such a claim lacks specific utility. However, this situation does not apply here. Applicants are not making a claim to a specific EST with an unknown target. Rather, Applicants are making a claim to a composition (claim 1),

which can contain mRNA as a template, as recited in dependent claims (claims 8 and 9). The fact that a population of mRNAs may contain sequences which constitute what others have described as ESTs does not negate the utility of the claimed invention (for instance, as a composition that may be used to make a labeled cDNA copy of mRNAs in a sample). The rationale of the Action's rejection would be the same as saying that a claim to a cDNA library lacks utility just because some of the clones in the library comprise ESTs or the sequences of genes of yet unknown function. Instead, the library would still be useful as a source for cloning a gene of interest. In the present case, the mere fact that a population of mRNAs may contain what are regarded as EST sequences does not detract from the utility of the claimed compositions.

The specification makes clear why the claimed invention has specific and substantial utility. Just as one example, the specification states:

> By incorporation of different labels (two or more) into a nucleic acid molecule, the invention may provide more sensitive probes since the different labels have different attributes and characteristics and those different characteristics and attributes can be used to facilitate detection of the probe. . . . In one example, a population of nucleic acid molecules from one tissue or cell (e.g. mRNA molecules) may be labeled with one detectable label while a second population of nucleic acid molecules from a different cell or tissue may be labeled with a second detectable label. Such differential labeling should allow for simultaneous detection and analysis of multiple nucleic acid samples, thus reducing costs and increasing throughput. For example, a combination of different probes having different labels can be reacted on an array and the gene expression profile can be determined for each different sample based on the label detected. *See* published specification at paragraph [0015].

Applicants respectfully submit that a skilled artisan would find such a use for the claimed invention to be specific and substantial, as required to satisfy the utility requirement. Accordingly, Applicants respectfully request that this ground for rejection be withdrawn. Furthermore, in light of the satisfaction of the utility requirement, Applicants further request that the rejection for lack of enablement also be withdrawn.

C. Rejection of Claims Under 35 U.S.C. § 103(a)

Claims 1, 3, 5, 6, 8, 9, 55, 59, 62, 64, 65, 71, 76, and 78 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 6,709,815 ("Dong") in view of U.S. Patent No. 6,906,244 ("Fischer"). Applicants respectfully traverse this ground for rejection.

The Action cites Dong for the alleged teaching of the use of "2 or more different, modified, monomeric deoxyribonucleotide triphosphates". As argued by the Action, in response to Applicants' argument in the previous Office Action response, "Dong *et al.*, at column 44, provides a definition for "nucleotide analog" and states that this encompasses both singular and plural uses." *See* Action at page 4. However, Applicants have reviewed column 44 of Dong and have not ascertained how this portion of the specification discloses "both singular and plural uses."

The relevant section of Dong's specification reads:

> The term "nucleotide analog" as used herein refers to modified or non-naturally occurring nucleotides such as 7-deaza purines (i.e., 7-deaza-dATP and 7-deaza-dGTP). Nucleotide analogs include base analogs and comprise modified forms of deoxyribonucleotides as well as ribonucleotides. As used herein the term "nucleotide analog" when used in reference to targets present in a PCR mixture refers to the use of nucleotides other than dATP, dGTP, dCTP and dTTP; thus, the use of dUTP (a naturally occurring dNTP) in a PCR would comprise the use of a nucleotide analog in the PCR. A PCR product generated using dUTP, 7-deaza-dATP, 7-deaza-dGTP or any other nucleotide analog in the reaction mixture is the [*sic*] to contain nucleotide analogs. *See* Dong at column 44, lines 51-64.

Applicants respectfully submit that this passage merely discloses that any one of a number of different types of compounds, *e.g.*, deaza-NTPs or dUTP, belong to the class of nucleotide analogues that are alternative forms of nucleotide analogs that may be used in the practice of Dong's invention, not that multiple members of these can be used simultaneously as claimed in the present invention. As a result, the disclosure in column 44 of Dong as cited by the Action does not provide any broader a definition of "a nucleotide analogue" so as to encompass the use of "two or more" nucleotide analogs than does column 11 of Dong, as previously pointed to by Applicants in the

previous Office Action response. Thus, Applicants respectfully submit that Dong does not teach "2 or more different, modified, monomeric deoxyribonucleotide triphosphates," as presently claimed.

This shortcoming of Dong is not remedied by the disclosure of Fischer which discloses the use of a single modified deoxyribonucleotide triphosphate. Accordingly, the combination of cited references fail to teach each and every element of the claimed invention as required to establish a *prima facie* case of obviousness, and Applicants respectfully request withdrawal of this rejection.

D. Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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